

REMARKS

1. Introduction

Claims 1-58 are pending in this application. Claims 3-6, 9, 11, 24, 26-27, 29, 40 and 55-58 have been withdrawn from consideration. In the Office Action dated May 20, 2004, the Examiner took the following action: (1) objected to the drawings as failing to comply with 37 C.F.R. § 1.84(p)(5); (2) objected to claims 17, 33 and 47 for informalities; (3) rejected claims 1-2, 7-8, 19, 21, 34-35, 38-39, 48, 50-52 and 54 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,793,326 to Shishido; (4) rejected claims 1-2, 7-8, 19, 21, 34-35, 38-39, 48, 50-52 and 54 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,301,061 to Nakada et al.; (5) rejected claims 1-2, 19-21, 34-35 and 48-52 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,699,178 to Koda; (6) rejected claims 10, 12-13, 16-18, 41-43 and 46-47 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido as applied to claims 1 and 34 above, in view of U.S. Patent No. 6,551,278 to Geitz and further in view of U.S. Patent No. 5,899,850 to Ouchi; (7) rejected claims 22-23, 25, 28 and 32-33 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido in view of U.S. Patent No. 6,551,278 to Geitz and further in view of U.S. Patent No. 5,899,850 to Ouchi; (8) rejected claims 12-15, 41 and 43-45 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido as applied to claims 1 and 34 above, and in view of U.S. Patent No. 5,603,699 to Shine; (9) rejected claims 22, 25, 30 and 31 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido in view of U.S. Patent No. 5,603,699 to Shine; and (10) rejected claims 36-37 and 53 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,793,326 to Shishido as applied to claims 34 and 53 above, and in view of U.S. Patent No. 5,337,734 to Saab.

2. The Disclosed Invention

The disclosed embodiments of the invention will now be discussed in comparison to the applied references. Of course, the discussion of the disclosed embodiments, and the discussion of the differences between the disclosed embodiments and the subject matter

described in the applied references, do not define the scope or interpretation of any of the claims. Instead, such discussed differences merely help the Examiner appreciate important claim distinctions discussed thereafter.

As the Examiner is undoubtedly aware, endoscopes are commonly used to obtain biopsy samples inside the human body. A biopsy samples are typically obtained by introducing an insertion tube of an endoscope into the body and positioning the distal end of the insertion tube adjacent to the sample site. A biopsy sampling device is then inserted through a biopsy channel formed in the insertion tube until the sampling device projects from the distal end of the insertion tube. After the sample is taken, the biopsy sampling device is withdrawn from the insertion tube through the biopsy channel. This conventional procedure can create a substantial risk of cross-contamination because the insertion tube of the endoscope as well as the entire biopsy channel are exposed to the external environment.

Protective endoscope sheaths have been developed to minimize the risk of cross-contamination when conducting endoscopic procedures. However, since the endoscope sheaths completely encapsulate the distal end of the insertion tube, they would prevent external access to the biopsy channel at the distal end of the insertion tube. Therefore, the use of endoscope sheaths prevents the biopsy channel in the insertion tube and from being used to obtain biopsy samples in a conventional manner. However, special endoscopes and protective sheaths have been developed in which a biopsy channel is formed inside or outside the sheaths, and the endoscope insertion tube is specially adapted to accommodate the channel. Unfortunately, it is often not possible or practical to use protective sheaths having a biopsy channel with conventional endoscopes.

A primary goal of the disclosed invention is to allow a biopsy sample to be obtained using a conventional endoscope encapsulated by a protective sheath that does not have a biopsy channel. This goal is achieved by attaching a biopsy sampling device to the outside of the sheath in a manner that places a collection member of the sampling device adjacent the distal end of the insertion tube and so that it can be observed when a sample is to be taken. Significantly, since the sheath completely encapsulates the distal end of the endoscope insertion tube, the insertion tube is protected from cross-contamination while still allowing a biopsy sample to be obtained.

3. The Prior Part

The patent to Shishido has been cited for disclosing a sheath assembly adapted for use with an endoscope insertion tube including a sheath having a body portion adapted to partially encapsulate the working end of the insertion tube, and a collection member in the form of a brush that is attached to the sheath. However, the brush that is considered to be the collection device is instead of a guide means that is used to guide the insertion tube around curves or bends. The Shishido patent does not suggest that the brush or any of the other disclosed guide means can be used to collect a biopsy sample. Furthermore, this Shishido patent does not disclose the use of a protective sheath completely encapsulating the distal end of an endoscope. Instead, the guide means, *i.e.* the brush, is attached to an end cap that fits over the end of the endoscope itself rather than over a sheath. Significantly, the entire distal end of the endoscope is exposed, thereby creating the distinct possibility of cross-contamination.

The patent to Nakada *et al.* has been cited for disclosing a sheath assembly in Figure 14 for use with an insertion tube including a sheath (9) partial encapsulating the working end of the insertion tube (2) and a collection member (41) attached to the sheaths and including a collection member proximate the distal end portion. However, the “sheaths” disclosed in the Nakada *et al.* patent are instead reinforcing sheaths, one of which includes a brush 41 at its distal end. There is no suggestion in the Nakada *et al.* patent that the brush can or should be used to collect biopsy samples. Instead, the patent teaches that the purpose of the brush 41 is “for removing stains and aggregations of material.” Nakada *et al.* also state that the brush “projects in the tip direction so that, when the sheath is operated to advance and retreat, the stains and aggregations will be removed with the brush.” [Col. 7, lines 8-12]. It is therefore clear that the Nakada *et al.* patent does not suggest that the brush 41 can be used to obtain biopsy samples. Additionally, as with the Shishido device, the tip of the fiber scope 2 projects through the distal end of the “sheath,” as best shown in Figure 16. As a result, on the fiber scope 2 would be exposed to cross-contamination if it was used for an endoscopic procedure. Furthermore, there would be no need to use the brush 41 to obtain biopsy samples since the open end of the “sheath” would allow a biopsy to be obtained in the conventional manner by simply inserting a collection device through the channel.

The patent to Koda has been cited for disclosing in Figure 5 a sheath assembly for use with an endoscopic insertion tube including a sheath having a body portion (50) adapted to partially encapsulate the working end of the insertion tube, and a collection member (55) attached to the sheath and including a collection member proximate the distal end portion. However, Figure 5 of the Koda patent shows an auditory canal cleaning apparatus having a main body 50 including an ear-pick barrel 53 with an opening 52 for allowing a fiber-optic scope 41 to pass through it. Projecting from the distal end of the main body 50 are an irradiating part 54 for irradiating the auditory canal 54 and an earwax removing part (scraping part) 55 for removing earwax. However, the body portion 50 cannot be considered a sheath. Instead, it becomes the distal end of an endoscope as shown in Figure 7. Thus, the Koda patent simply discloses an endoscope design having an internal channel and a device that the Examiner considers to be a biopsy collection device. The Koda patent does not disclose the use of a protective sheath that completely encapsulates the distal end of an endoscope. Therefore, the use of a body portion 50 having an internal channel that are completely exposed to the external environment would leave the body portion 50 open to cross-contamination. Finally, as with the Nakada *et al.* device, there presence of a channel open at the distal end of the device would allow a biopsy to be obtained in the conventional manner by simply inserting a collection device through the channel.

The patent to Geitz, the patent to Ouchi, and the patent to Shine you have been cited in combination with the patent to the Shishido. According to the Examiner, the patent to Shishido teaches the basic concept of an endoscope encapsulated by a sheath having a collection member at its distal end, and these other patents disclose the concept of movable cover member that either partially covers or exposes the collection member. However, as explained above, the Shishido patent does not, in fact, teach the basic concept of an endoscope encapsulated by a sheath having a collection member at its distal end. The patent to Geitz discloses an x-ray catheter 1 having and x-ray source 2 within a shield 3 to which retractable needles 5 are pivotally mounted. The needles 5 are not used to collect biopsy samples. Instead, if they are hollow, they can be used to deliver a therapeutic substance, or they can be retained in tissues for use as a marking or locating device for future procedures. [Column 6, lines 16-31]. Thus the sheath 8 does not selectively cover a biopsy sampling device. The patent to Ouchi has been cited for disclosing an endoscopic system having a collection member comprising a brush 2, which is

enclosed by a cover member when the brush is not in use. However, the brush is inserted through an internal channel 12 in the endoscope rather than attached to a sheath enclosing an endoscope. It is a relatively simple matter to provide a cover that selectively encloses a biopsy collection device when the biopsy collection device can be manipulated through an endoscope channel. It is significantly more difficult to perform this function when the biopsy collection device is not accessible through a channel in the endoscope because it is attached to a sheath that encapsulates the endoscope. Finally, the patent to Shine has been cited for disclosing a hinged cover member for sharp collection members movable between two positions that alternately cover or expose the collection member. The Shine patent discloses a needle guard assembly in which a generally cylindrical needle guard pivots upwardly to expose a needle. Thus, the cover encloses a delivery device, *i.e.*, the needle, rather than a collection device. There is also no suggestion that the needle guard assembly could be used with an endoscope, nor is there any suggestion about how the cover could be actuated to its open position if the needle guard assembly was attached to the distal end of an endoscope and thus not accessible through a channel in the endoscope.

#### 4. The Claim Rejections

Claim 1 has been rejected as being anticipated by either the patent to Shishido, the patent to Nakada *et al.* or the patent to Koda. Amended claim 1 specifies that the claimed sheath assembly includes a sheath having a body portion that completely encapsulates the working end of an insertion tube when the sheath is positioned on the insertion tube. The claim further specifies that a biopsy sampling device is attached to the sheath, and that the biopsy sampling device includes a collection member proximate the distal end portion of the sheath.

To anticipate a claim, a prior art reference must disclose every feature of the claim exactly as specified. As explained above, none of the three references considered to anticipate claim 1 disclose a sheath that completely encapsulates the working end of an insertion tube, and that has a biopsy sampling device attached to the sheath adjacent the distal end. The Shishido sheath leaves the entire distal end of the endoscope exposed, and the brush is described as being a guide means rather than a biopsy collection device. The reinforcing sheath disclosed in the Nakada *et al.* patent allows the tip of the fiber scope 2 to project through its

distal end, and the brush is described as being for cleaning “stains and aggregations” rather than for collecting biopsy samples. The main body of the auditory canal cleaning apparatus disclosed in the Koda patent becomes part of an endoscope rather than serving as a sheath for an endoscope, and the distal end of the main body is thus not encapsulated by a sheath. Instead, the channel in the sheath is exposed to the external environment. Claim 1 is therefore novel in view of the cited references.

Claim 34 has been rejected as being anticipated on the same basis used for the rejection of claim 1. Claim 34 specifies an endoscope having an elongated insertion tube, and a sheath including a body portion completely encapsulating a distal portion of the insertion tube. As explained above, none of the three references cited for anticipating claim 34 disclose an insertion tube completely encapsulated by a sheath. Claim 34 further specifies a biopsy sampling device attached to the sheath including a collection member proximate an end of the body portion. As explained above, the cited references do not disclose a sheath having a biopsy collection device in which the sheath completely encapsulates an insertion tube.

Claim 50 is directed to a method in which an endoscope insertion tube is inserted into a protective sheath that completely encapsulates a major portion of the body portion including the distal end. As previously explained, the prior art does not disclose the sheath completely encapsulating a distal end of an insertion tube. Claim 50 further specifies that sheath has a biopsy sampling device attached to it that includes a collection member proximate the distal end of the body portion. Although the prior art may disclose biopsy devices, they do not disclose biopsy devices attached to a sheath that completely encapsulates an endoscope insertion tube. Claim 50 is thus novel over the prior art.

The remaining independent claim is claim 22, which has been rejected as being obvious over the patent to Shishido in view of either the patent to Shine or the patent to Geitz and the patent to Ouchi. However, for both rejections, the Shishido patent is being relied on for disclosing a sheath encapsulating an endoscope and having a biopsy collection device attached to its distal end. But as previously explained, the Shishido patent does not disclose a sheath completely encapsulating the distal end of an endoscope. Nor does the Shishido patent disclose a biopsy collection device; instead it discloses a guide means at the distal end of an endoscope. The remaining references have been cited for disclosing a removable cover for a collection

device. However, the “covers” shown in the Geitz patent and in the Shine patent enclose medication delivering needles rather than a biopsy collection device. While the Ouchi patent does disclose a cover for a biopsy collection device, the collection device is inserted through the channels of an endoscope rather than being attached to the end of a sheath completely enclosing the distal end of an endoscope. Certainly there is no teaching in any of these references how the cover could be manipulated between two positions if the distal end of the endoscope was encapsulated and thus not accessible to serve as an access path for manipulating the “covers.” Finally, the Examiner has not pointed out any place in any of the references where there is any suggestion of the desirability of combining their respective teachings. For all of these reasons, claim 22 is not obvious over the cited references.

The Section 112 rejection of the claims and the objection to the drawings are being obviated by amending the relevant claims and by amending the specification.

5. Conclusion

Insofar as all of the claims remaining in this application are now in proper form and clearly allowable over the cited references, favorable consideration and a notice of allowance are earnestly solicited.

Respectfully submitted,

DORSEY & WHITNEY LLP



Edward W. Bulchis  
Registration No. 26,847  
Telephone No. (206) 903-8785

EWB:dms

Enclosures:

- Postcard
- Check
- Fee Transmittal Sheet (+ copy)

DORSEY & WHITNEY LLP  
1420 Fifth Avenue, Suite 3400  
Seattle, WA 98101-4010  
(206) 903-8800 (telephone)  
(206) 903-8820 (fax)

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